

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**NOVARTIS PHARMACEUTICALS
CORPORATION,
NOVARTIS PHARMA AG, and
NOVARTIS INTERNATIONAL
PHARMACEUTICAL LTD.,**

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.

Defendant.

Civil Action No: 05-1887 (DMC)

**CONTAINS CONFIDENTIAL
INFORMATION PURSUANT TO
THE CONFIDENTIALITY ORDER**

FILED UNDER SEAL

**TEVA PHARMACEUTICALS USA, INC.'S REPLY MEMORANDUM
IN FURTHER SUPPORT OF MOTION TO DISMISS PLAINTIFFS NOVARTIS
PHARMACEUTICALS CORPORATION AND NOVARTIS PHARMA AG
FOR LACK OF ARTICLE III STANDING**

LITE DEPALMA GREENBERG & RIVAS, LLC

Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, 12th Floor
Newark, New Jersey 07102
(973) 623-3000
alite@ldgrlaw.com
mpatunas@ldgrlaw.com
matarantino@ldgrlaw.com

GOODWIN PROCTER LLP

Shepard M. Remis
Roland H. Schwillinski
John T. Bennett
53 State Street
Boston, MA 02109
(617) 570-1000
sremis@goodwinprocter.com
rschwillinski@goodwinprocter.com
jbennett@goodwinprocter.com

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

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INTRODUCTION

In their opposition, Plaintiffs concede—as they must—that only the owner of a patent or an exclusive licensee under the patent has Article III standing to assert a claim for patent infringement. Plaintiffs also do not dispute that the Bermuda corporation Novartis International Pharmaceutical Ltd. (“NIP”) is the sole owner of the ’937 patent, and consequently that neither NPC or NPAG has standing as a patent owner in this case. Instead, Plaintiffs now claim for the first time—contrary to their position during discovery—that NPC and NPAG are exclusive licensees under the ’937 patent and have standing on that basis.

Plaintiffs’ new arguments lack any merit. Contrary to Plaintiffs’ assertions, nothing in the Asset Sale Agreement with SmithKline Beecham PLC and its affiliates (collectively, “SKB”) purports to grant an exclusive license under the ’937 patent to either NPC or NPAG. [REDACTED]

[REDACTED] Furthermore, the size and scale of the asset sale transaction, the sophistication of the parties, and the tax benefits that Novartis received by assigning the famciclovir patents to a

¹ ASA refers to the Asset Sale Agreement, a copy of which is attached to the declaration of Daniel Wipfli.

Bermuda entity all reinforce the conclusion that Plaintiffs did not intend that NPC or NPAG would have an exclusive license under the patent. Since NPC and NPAG are not exclusive licensees under the '937 patent, they do not have standing to assert a claim for patent infringement and must be dismissed from this case.

ARGUMENT

I. The Asset Sale Agreement Does Not Grant Either NPC or NPAG an Exclusive License Under the '937 Patent.

Plaintiffs cite nothing in the language of the Asset Sale Agreement with SKB to support their assertion (at pp. 9-10) that NPC and NPAG both received exclusive licenses under the '937 patent. The reason, of course, is that no such language exists in the Agreement. Plaintiffs' claim to a written exclusive license is—to use their phrase—“nothing more than wishful thinking.”

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Nothing in the Asset Sale Agreement states that either NPC or NPAG is granted any kind of license under the '937 patent or any of the other patents assigned to NIP. Indeed, Plaintiffs concede (at p. 8) that the Agreement "does not explicitly include the phrase 'exclusive license'" [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2 [REDACTED]

Plaintiffs are confusing two different types of assets.

Plaintiffs also argue (at p.8) that it is the substance of the rights transferred, than the characterization of those rights, that controls whether a document says an exclusive license.³ But here, nothing in the Asset Sale Agreement NPC or NPAG *any* rights at all in the '937 patent. Since the Agreement does nowhere provide that either NPC or NPAG has the right to exclude others making, using or selling the patented invention, it is not an exclusive license. Plaintiffs' assertion that NPC and NPAG have written exclusive licenses to the -in-suit must be rejected.

³ See, e.g., *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 n.7 (Fed. Cir. 2007). For example, if an “exclusive license” transfers all substantial rights in the patent it is an assignment, regardless of the name by which it is called. See, e.g., *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991).

II. There Is No Factual Basis For Plaintiffs' Implied License Claim.

Plaintiffs' backup argument (at pp. 10-15) is that even if the Asset Sale Agreement did not expressly grant NPC and NPAG an exclusive license under the patent—which it plainly did not—a license should be implied based upon the relationship and course of conduct between NIP, NPC and NPAG.⁴ Again, Plaintiffs are engaging in wishful thinking. There is no reasonable basis for finding an implied license on the facts of this case.

A. The Asset Sale Agreement Precludes Any Implied License.

The first problem with Plaintiff's "implied license" argument is that it is contrary to the plain language of the Asset Sale Agreement. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

B. The Circumstances of the Transaction Confirm That No Exclusive License Can Be Implied.

Even leaving aside the express language of the Asset Sale Agreement, the circumstances of the sale of the '937 patent from SKB to NIP leave no room for

⁴ Plaintiffs also argue in a footnote (at p. 9 n.3) that there is an oral exclusive license, but proffer no evidence to support that assertion.

Plaintiffs to argue that an exclusive license can be implied. [REDACTED]

[REDACTED]

[REDACTED] The precise terms of that transaction are set forth in minute detail in the Asset Sale Agreement and a series of ancillary documents and agreements spanning some 727 pages. Trainor Supp. Decl. ¶ 2. All of these documents were undoubtedly reviewed by teams of lawyers on both sides. Where the parties intended to grant licenses, they did so expressly. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Given the sophistication of the parties and the evident care with which the agreements were drafted, if the parties had intended for NPAG or NPC to have an exclusive license they would have said so explicitly.

There is no great mystery as to why Plaintiffs chose not to grant an exclusive license to NPC or NPAG. The decision to assign the patent rights to NIP, a Bermuda corporation, was part of a tax planning strategy designed to reduce Novartis's overall tax liability on the sale of Famvir®. Plaintiffs do not and cannot dispute that Bermuda is well known as a tax haven. Assigning patent rights to an

affiliated corporation in a low-tax country is a very common tax planning tactic among large multinational enterprises, especially in the pharmaceutical industry.

Eli Lilly & Co. v. Commissioner, 856 F.2d 855 (7th Cir. 1987) illustrates the basic strategy. In that case, the pharmaceutical manufacturer Eli Lilly (Lilly) sought to reduce its taxable income by creating a Puerto Rican subsidiary to manufacture one of its most profitable drugs.⁵ Lilly transferred title to the drug patents and other manufacturing intangibles to the Puerto Rican subsidiary (Lilly P.R.), which manufactured and sold the product to Lilly at a price calculated to earn a proper division of earnings between parent and subsidiary. *Id.* at 858. Section 482 of the Internal Revenue Code, 26 U.S.C. § 482, and the regulations thereunder require the transfer prices for such transactions between related corporations to be set at a level consistent with what unrelated corporations would have agreed on in an arms-length transaction under the same circumstances. *See generally* Treas. Reg. § 1.482-1(b). The Internal Revenue Service argued that the transfer of the patents could be disregarded and consequently that Lilly P.R.'s income derived from the patents should be attributed to Lilly in setting the transfer prices. The Tax Court, however, rejected this position and the Seventh Circuit affirmed, holding that as Lilly P.R. was the legal owner of the patents, income

⁵ At the time, Puerto Rico was a low-tax jurisdiction as a result of tax incentives provided by Federal and Puerto Rican law. *Eli Lilly*, 856 F.2d at 857.

derived from the patents was properly attributable to Lilly P.R. Thus, by assigning the patents and outsourcing manufacturing operations to Lilly P.R., Lilly avoided paying U.S. taxes on income attributable to the manufacture of the product.

Based on the new information that Plaintiffs have provided in their opposition, it appears that Novartis is engaged in a variation on this strategy.

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] Mr. Wipfli does not specify the price at which NIP sells to NPAG, but presumably it includes a markup over NIP's costs, *i.e.*, a profit to NIP. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] This arrangement shields a portion of the total profit that Novartis earns manufacturing and selling Famvir® from U.S. taxes because no U.S. taxes are paid on the profits earned by NIP and NPAG.

For Novartis to take full advantage of this structure, however, it is important that NPC not have an exclusive license in the patents owned by NIP. A license is a form of intangible property, *see* Treas. Reg. 1.482-4(b)(4), and in economic terms there is no difference between ownership of an exclusive license to make, use and sell a patented invention and ownership of the patent itself. *See, e.g., Waterman,*

138 U.S. at 256; *Vaupel*, 944 F.2d at 875. Thus, if NPC had been granted an exclusive license under those patents, then some portion of NIP's profits from the manufacture of famciclovir would at least potentially be attributable to NPC and subject to U.S. taxation—just as if NIP owned the patent itself. *See generally* Treas. Reg. 1.482-4 (methods for determining taxable income in connection with a transfer of intangible property). This explains why Plaintiffs chose not to grant NPC an exclusive license.

Plaintiffs protest (at pp. 13-14) that their corporate structure should not be viewed as a tax avoidance scheme because NPC—the United States entity—pays U.S. taxes on its profits. This argument misses the point. NPC may pay taxes on *its* profits, but Plaintiffs do not allege that NPC pays U.S. taxes on the profits that *NIP* earns from manufacturing the API, which represents part of the value of the famciclovir product. The benefit of the arrangement to Novartis comes from the fact that NIP's profits are not taxed in the United States or attributed to NPC under § 482. Notably, Plaintiffs do not proffer any alternative explanation for their decision to assign the patent rights to a Bermuda corporation. If Plaintiffs were not seeking to gain a tax advantage, it would have been much simpler to simply assign the patents to NPC. Plaintiffs' decision to vest title to the patents in NIP only makes sense as part of a tax planning strategy.

Of course, there is nothing wrong with Novartis having structured its affairs so as to minimize its U.S. tax liability. “Taxpayers are . . . generally free to structure their business affairs as they consider to be in their best interests, including lawful structuring (which may include holding companies) to minimize taxes.” *Commissioner v. First Sec. Bank*, 405 U.S. 394, 398 n.4 (1972). But as the Federal Circuit has made clear, related corporations cannot “enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure.” *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004). Having taken the tax benefits that come from having all of the patent rights vested in NIP, Novartis must now accept the burden that NPAG and NPC do not have sufficient rights to confer patent standing.

C. The Cases Relied on By Plaintiffs Are Inapposite.

Plaintiffs’ assertion that an exclusive license should be implied here is based primarily on the non-precedential decision in *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 Fed. App’x 697 (Fed. Cir. 2008) and on *Ricoh Co., Ltd. v. Nashua Corp.*, 947 F. Supp. 21 (D.N.H. 1996). But the facts of these cases are not even remotely comparable to the facts of this case. First of all, in *Aspex* the purported licensee and licensor were small companies owned by a family trust—not subsidiaries of a large and highly sophisticated multinational enterprise like the Plaintiffs in this case. *See Aspex*, 288 Fed. App’x at 699, 706. While it is certainly

plausible that a small family-owned business might enter into an exclusive licensing arrangement without putting anything in writing, it is inconceivable that the Plaintiffs in this case would have done so.

Even more significantly, in neither *Aspex* nor *Ricoh* did the parties disclaim any implied agreement, as NPC and NPAG did in the Asset Sale Agreement. Moreover, in neither case was there any indication that the parties had sought to achieve tax benefits by transferring or assigning patent rights to an entity in a low-tax jurisdiction. As one commentator on the cases has explained, “[t]his type of evidence, which was absent in *Ricoh*, would tend to refute a contention that the parties intended that the [non-patent holder] would have an exclusive license.” Robert A. Matthews, Jr., *A Potential Hidden Cost of a Patent-Holding Company: The Loss of Lost-Profit Damages*, 32 AIPLA Q.J. 503, 533 (2004). In sum, while it may have been reasonable to imply an exclusive license in *Aspex* and *Ricoh*, it is not reasonable to do so under the very different facts of this case.

D. NPC and NPAG Cannot Both Be Exclusive Licensees.

Finally, Plaintiffs’ assertion that NPC and NPAG are *both* exclusive licensees defies logic. By definition, NPC and NPAG cannot both be exclusive licensees in the same territory and field of use. “To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee’s express or implied

promise that others shall be excluded from practicing the invention within that territory as well.” *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995) (en banc).⁶ Here, Plaintiffs contend (at p. 4) that NPAG has an exclusive right to manufacture patented product, with a right to sublicense that right to other entities, and that NPAG has an exclusive right to sell, with the right to sublicense to other entities. If that is the case, then neither NPC nor NPAG has a promise that other parties shall be precluded from practicing the invention because either NPC or NPAG can always authorize another party to practice the patented invention. Thus even accepting Plaintiffs’ unsupported assertions at face value, neither NPC nor NPAG can be deemed an exclusive licensee for standing purposes.

III. Plaintiffs’ Declarations From Previously Undisclosed Witnesses Must Be Disregarded.

To resolve the issues presented by this motion, the Court does not need to look any further than the face of the Asset Sale Agreement and related documents

⁶ Plaintiffs (at p. 7) cite the pre-*Rite-Hite* decisions in *Weinar v. Rollform, Inc.*, 744 F.2d 797 (Fed. Cir. 1984) and *Amgen, Inc. v. Chugai Pharm. Co. Ltd.*, 808 F. Supp. 894 (D. Mass. 1992) for the proposition that the “sole distributor” of a product in the United States has standing to sue for patent infringement. The *en banc* Federal Circuit rejected this interpretation in *Rite-Hite*, distinguishing *Weinar* and explaining that “[t]he grant of a bare license to sell an invention in a specified territory, even if it is the only license granted by the patentee, does not provide standing without the grant of a right to exclude others.” 56 F.3d at 1538. Moreover, the language Plaintiffs cite from *Amgen* is *dicta* because the district court in that case found no exclusive license, 808 F. Supp. at 904, and the Federal Circuit affirmed, see *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1033-34 (Fed. Cir. 1995).

like the assignment of patents to NIP. The Court cannot, however, consider the conclusory assertions in the declarations of Daniel Wipfli and Jeffrey Dembiec regarding the supposed existence of an exclusive licensing arrangement. First, neither Mr. Wipfli nor Mr. Dembiec was previously identified in discovery as required by Fed. R. Civ. P. 26(a) and (e). Plaintiffs bear the burden of establishing standing, *see, e.g., Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1338 (Fed. Cir. 2007), and thus were required to identify any witnesses they might use to support their standing claim. Fed. R. Civ. P. 37(c) provides that “[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), *the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing or at a trial*, unless the failure was substantially justified or is harmless.” (Emphasis added.)

In this case, there is no justification for Plaintiffs’ failure to timely identify Mr. Wipfli and Mr. Dembiec. Plaintiffs were aware of the standing issue early on in the litigation. Teva raised the standing issue in its first set of interrogatories (Trainor Decl. Ex. D) served in August 2005 and continued to press the issue through additional discovery requests and motion practice in 2007. *See* Trainor Decl. Exs. F-G. But instead of disclosing these witnesses, Plaintiffs instead took the position that there were no license agreements granting patent rights to NPC or NPAG. *See* Trainor Decl. Ex. G (Tr. of April 9, 2007) at 38:24-39:1 (“We told

[Teva] we could find no licenses under the '937 patent, all granted between any of the Novartis entities. That was our answer, and it is a true answer.'") Plaintiffs' failure to identify these witnesses is prejudicial to Teva because it prevented Teva from deposing them and whether there is any factual basis for their statements. Accordingly, these declarations must be excluded under Rule 37(c).

But in any event, these declarations on their face establish that Mr. Wipfli and Mr. Dembiec do not have personal knowledge of the relevant facts because neither of these witnesses was working for Novartis in 2000 when the Asset Sale Agreement was executed and the patent was assigned to NIP. Mr. Wipfli has only been working within the Novartis group of companies since 2002, and Mr. Dembiec only since March 2007. Wipfli Decl. ¶ 1; Dembiec Decl. ¶ 1. Thus neither Mr. Wipfli nor Mr. Dembiec has any firsthand knowledge of the purpose or effect of these transactions. Accordingly, their testimony regarding the supposed existence of an exclusive license is inadmissible under Fed. R. Evid. 602 (lack of personal knowledge) and 802 (hearsay).

IV. The Standing Issue Must Be Resolved By the Court Prior to Trial.

Plaintiffs argue (at pp. 17-19) that there are disputed issues of fact regarding NPC's and NPAG's standing and accordingly that the issue should be deferred until trial. For all of the reasons set forth above, Plaintiffs have not produced any admissible evidence sufficient to carry their burden of establishing that NIP and

NPAG are exclusive licensees. To the contrary, the plain language of the Asset Sale Agreement shows that they are not.

But to the extent that the Court concludes that there is a disputed issue of material fact, it must be resolved by the Court prior to trial. Standing is a threshold matter that must be resolved before a court can adjudicate the merits of a dispute.

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 88-89, 94-95 (1998).

Moreover, the Federal Circuit has held that in patent cases, the existence of standing is to be decided by the Court, not by a jury. *DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1291-92 (Fed. Cir. 2008). To the extent that there are any disputed factual issues, the Court must decide them either on the papers or following an evidentiary hearing. *See, e.g., McCann v. George W. Newman Irrevocable Trust*, 458 F.3d 281, 290 (3d Cir. 2006) (where jurisdiction is challenged, the court decides the issue by weighing the evidence, and “[i]f there is a dispute of a material fact, the court must conduct a plenary hearing on the contested issues prior to determining jurisdiction.”).

CONCLUSION

For all of the foregoing reasons, as well as those set forth in our opening brief, NPAG and NPC must be dismissed as plaintiffs.

Dated: September 21, 2009

Respectfully submitted,

s/ Michael E. Patunas

**LITE DEPALMA GREENBERG &
RIVAS, LLC**

Allyn Z. Lite

Michael E. Patunas

Mayra V. Tarantino

Two Gateway Center, 12th Floor

Newark, New Jersey 07102

(973) 623-3000

alite@ldgrlaw.com

mpatunas@ldgrlaw.com

mtarantino@ldgrlaw.com

GOODWIN PROCTER LLP

Shepard M. Remis

Roland H. Schwillinski

John T. Bennett

53 State Street

Boston, MA 02109

(617) 570-1000

sremis@goodwinprocter.com

rschwillinski@goodwinprocter.com

jbennett@goodwinprocter.com

Attorneys for Defendant

Teva Pharmaceuticals USA, Inc

CERTIFICATE OF SERVICE

I, Mayra V. Tarantino, a full age certify under penalty of perjury that, on this day, I served a copy of (a) Teva Pharmaceuticals USA, Inc.'s Reply Memorandum in Further Support of Motion to Dismiss Plaintiffs Novartis Pharmaceuticals Corporation and Novartis Pharma Ag For Lack of Article III Standing, and (b) Declaration of Kelly M. Trainor with Exhibits, on all counsel of record via ECF and/or email.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

s/ Mayra V. Tarantino

Mayra V. Tarantino

Dated: September 21, 2009